

Non-Technical Abstract

Metastatic cancer of the colon or rectum is a rapidly fatal disease in the vast majority of affected patients despite combined modality therapy with radiation and chemotherapy. There is a large body of evidence in animal systems indicating that the immune system, including antibodies and immune cells termed lymphocytes, can be stimulated to recognize and destroy cancer cells. Experimental studies have been carried out in humans to attempt to induce these immune responses by means of a "vaccine." In this strategy, the patient is challenged with a vaccine which presents to the immune system the factor or factors (tumor antigen) which may allow the cancer cells to be recognized as "foreign" and rejected by the immune system. In the present study, antitumor immune responses will be elicited by a "polynucleotide vaccine." The polynucleotide vaccine consists of a highly purified and well defined DNA molecule which promotes expression of carcinoembryonic antigen (CEA), a protein found selectively on colon cancer cells and which flags these cells as abnormal to the immune system. The DNA is injected into the muscle of the patient where expression of the CEA gene induces an immune response to CEA. The immune response generated to the DNA expressed CEA should then allow recognition by the immune system of tumor cells containing CEA. This study will evaluate the safety of this method of gene delivery. Additionally, it will be determined whether this method of vaccination can successfully elicit an immune response to colon cancer cells in humans.